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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/160,076	09/24/1998	DAVID W. SCOTT	308072000110	5918

25226 7590 08/28/2003

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EXAMINER

WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
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1632

44

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/160,076	SCOTT ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 79-81 have been added. Claims 69-81 are pending and under consideration in the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's arguments filed 5-30-03, paper number 42, have been fully considered.

Specification

The first line of the specification needs updated to reflect that parent application 08/195874 is now US Patent 5,817,308.

The blanks on pg 16 must be filled in.

The title should be changed to reflect the claims are directed toward cells expressing fusion proteins of immunoglobulins.

Priority

The claim for domestic priority to 08/195874, now US Patent 5,817,308, is acknowledged.

Claim Rejections - 35 USC § 112

The rejection of claim 75 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn because the term "transduction" has been deleted.

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The rejection of claims 69-78 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been withdrawn.

The rejection of claims 69-78 under 35 U.S.C. 112, first paragraph, scope rejection, has been withdrawn.

1. Claim 70, 72 and 74 remain rejected and claims 80 and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of the phrase “a polypeptide containing... ..to which tolerance is desired to be induced” (claim 69) has been withdrawn because the phrase “to which tolerance is desired to be induced” has been deleted.

Claim 70 is indefinite as newly amended because it is not clear that the nucleic acid sequence in claim 69 was introduced into the cell. The phrase “wherein said nucleic acid sequence is a viral vector” would overcome this rejection.

Claim 72 is indefinite as newly amended because claim 69 is not directed toward a fusion protein and because the claim is dependent on two claims for two different things. Overall, the structure of the limitation is unclear. The phrase “wherein there are two or more copies of said nucleic acid sequence” would overcome this rejection.

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The rejection of claim 74 has been withdrawn because the phrase “or portion thereof” has been deleted.

The phrase “the first framework region of said N-terminal variable region” (claim 74) lacks antecedent basis in parent claims 69 or 70. It is not clear “the first framework region” must occur in the “N-terminal variable region” in parent claims 70 or 69. What is a “framework region”?

The term “autoimmune antigen” (claim 80) is indefinite for reasons of record regarding autoantigen.

Claim 81 is indefinite. The term “allergan” cannot be found in the art. The term is not defined in the dictionary or in the specification.

Claim Rejections - 35 USC § 102

The rejection of claim 69 under 35 U.S.C. 102(e) as being anticipated by Zanetti of record (US Patent 5,508,386, April 16, 1996) has been withdrawn because the claim now requires a non-tumor hematopoietic cell.

The rejection of claim 69 under 35 U.S.C. 102(b) as being anticipated by Zambidis of record (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) has been withdrawn because the claim now requires a non-tumor hematopoietic cell.

The following is a new rejection under 102:

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2. Claims 69 and 76-81 are rejected under 35 U.S.C. 102(b) as being anticipated by McDonnell et al. (Cell, 1989, Vol. 57, pg 79-88).

McDonnell taught a transgenic mice whose genome comprised a transgene comprising bcl-2-Ig fusion protein. Splenocytes and thymocytes were isolated from the mice in saline and media. The splenocytes and thymocytes are non-tumor lymphoid cells and are equivalent to the composition claimed because they have the structure claimed. The bcl-2-Ig fusion protein is equivalent to the fusion protein required in the claim because it has a heavy chain immunoglobulin and bcl-2. The bcl-2 protein inherently has at least one epitope as claimed. The cells of McDonnell inherently “induces tolerance to an antigen” because it has the same structure as the cell claimed. The phrase “for introduction into an individual” does not bear patentable weight because they are intended uses and may not occur. These intended uses do not bear patentable weight because they do not alter the structure of the composition. The composition of McDonnell inherently meets the functional limitation of “wherein upon introduction to the individual said composition induces tolerance to the antigen in the individual” because it has the structure claimed. The cells are syngeneic to mice of other strains (claim 76). The splenocytes and thymocytes are “bone marrow cells” (claim 77) because they originated in the bone marrow. The splenocytes and thymocytes inherently have “B-cells” (claim 78) because B-cells are found in the spleen and thymus. The splenocytes and thymocytes inherently comprise “hematopoietic cells” (claim 81) because they comprise pluripotent cells capable of differentiation. Claims 82

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and 83 are included because the metes and bounds of the limitations cannot be determined (see 112/2nd); therefore, bcl-2 is an autoimmunogen and an allergan.

Claim Rejections - 35 USC § 103

The rejection of claims 69-78 35 U.S.C. 103(a) as being unpatentable over Chambers (Feb. 1992, PNAS, USA, Vol. 89, pages 1026-1030) in view of Zambidis (Feb. 1, 1993, J. Cellular Biochem., Vol. 9, No. 17, Part B, page 251) has been withdrawn. Zambidis taught a tumor cell for producing a fusion immunoglobulin *in vitro* while chambers taught cells for inducing an immune response use *in vivo*. Therefore, the one of ordinary skill in the art would not have been motivated to combine Chambers and Zambidis.

Double Patenting

3. Claim 75 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 70. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Both claims require the nucleic acid is introduced into the cell via a viral vector.

Conclusion

No claim is allowed.

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Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

A handwritten signature in black ink, appearing to read 'Michael C. Wilson', with a long horizontal line extending to the right.

**MICHAEL WILSON
PRIMARY EXAMINER**